831458 – Trials@Home

Centre of Excellence – Remote Decentralised Clinical Trials

WP6 – PROMS

D6.5 Open call for additional technology partners

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Document History

Version	Date	Description
V1.1	02.02.2021	First draft
V1.2	17.03.2021	Addition quality report drafted by WP2
V1.3	17.05.2021	First draft circulated internally for review
V1.4	21.06.2021	Final version

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Abstract

The Trials@Home pan-European pilot (pan-EU pilot) study aims at comparing traditional clinical trial approaches to fully and hybrid RDCT approaches; as well as comparatively analyse the components (traditional clinical trial and hybrid and/or fully RDCT) in the pan-EU pilot and present and refine key performance indicators (KPIs) to qualify and quantify the flow of activities, subject perception, cost, quality and compliance.

Several technology/service providers were added to the Trials@Home project in order to ensure access to state-of-the-art technologies for the pilot Remote Decentralised Clinical Trial (RDCT) and to fulfil the relevant tasks identified in the Technology Package of WP2 TECH. This technology package and the proposed additional technology/service participants were selected through an external Request for Proposals (RfP).

The Trials@Home RfP has been developed in consultation with IMI to ensure compliance with the relevant EU and EU H2020 procedures and regulations. It described in detail the application requirements and procedures, timelines and templates to be used, as well as the eligibility and evaluation criteria and processes applied. A list of quality criteria was developed for the open call and published in "*D2.2 Detailed list of Quality assessment criteria and assessment procedures*".

This public report describes the process of selecting additional technology/service providers for providing technologies to be deployed in the Trials@Home pan-EU pilot study.

Acronyms and Definitions

Acronyms	Defined as
APIs	Application Programming Interface
BBB	Basic Building Blocks
CFR	Code of Federal Regulations
Clinpal	Internal clinical research platform
CRO	Contract Research Organization
EMA	European Medicines Agency
EU	European Union
ExBo	Executive Board
GDPR	General Data Protection Regulation
IIEP	The Independent Internal Expert Evaluation Panel OR Decision Committee
IMP	Investigational Medicinal Product
MyProjectPlaza	The project's internal collaboration platform
RDCT	Remote Decentralised Clinical Trial
RfI	Request for Information
RfP	Request for Proposals
SEO	Search Engine Optimization
SOPs	Standard operating procedure
TA	Therapeutic Area
WP	Work Package

Methods

The RfP process, including quality assessment and stepwise reduction/selection of technologies, is depicted in the figure 1. Prior to this process, which depicts the step-by-step approach and guidance for external technology/service providers, the Trials@Home consortium has developed an RfP package (Appendix 1).

Figure 1. RfP quality assessment process

The decision-making used to develop and launch this process responds to two objectives:

1) Objectively assess the extent to which the submissions meet the pre-defined quality criteria and BBB requirements.
2) Assess the extent to which the submissions are fit for purpose (as solution / as a technology/service provider) to support the Pan-European Pilot.

It has consisted of 6 steps, each of them being further detailed in this report:

1) RfP / Submission to Open call
2) Quality self-assessment survey
3) Reviewing materials including proposal, quality survey and supplementary documents
4) 1st Assessment committee meeting + rating
5) Technology/service provider pitch / demo
6) Decision / assessment report

Step 0 - Development of the Request for Proposals package (RfP)

In September 2020 a RfP working group combining expertise from all WPs was formed. One of the first tasks the working group started working on was the development of the RfP package for anticipated launch by the end of 2020.
The preparations to this external RfP included involving the technology scan WP TECH provided with a list of relevant technologies and solutions to be integrated to the pilot-study. This list was built from the conclusions of WP TECH internal knowledge on RDCTs, as well as external scanning conducted in 2020 via a Request for Information (RfI) available on the Trials@Home website (https://trialsathome.com/request-for-information/), in order to seek as many as possible candidate partners to submit their proposals in response to the Request for Proposals (RfP).

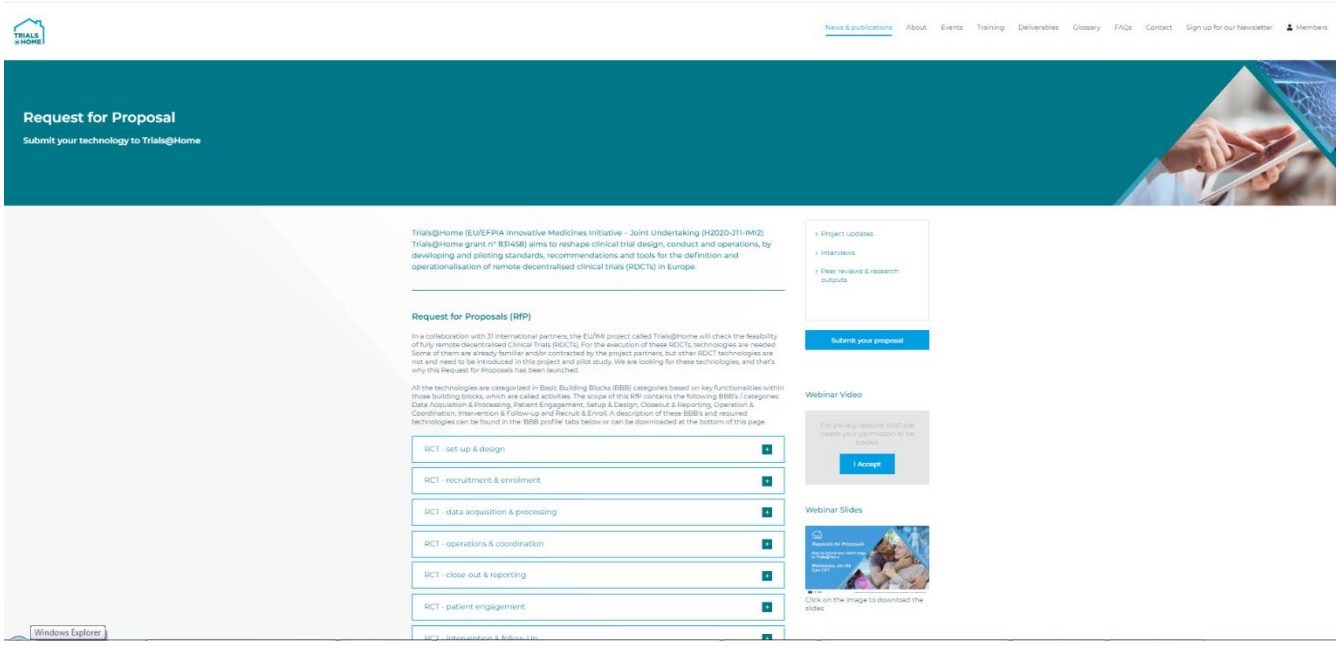
The RfI responders were also invited to apply to the RfP .

Open call
On 21 December 2021 an Open Call / Request for Proposals (Appendix 1) was launched on https://trialsathome.com. The scope of the RFP contained activities/functionalities that were not already familiar and/or contracted by the project partners and covered all Basic Building Blocks: *Data Acquisition & Processing, Participant Engagement, Setup & Design, Closeout & Reporting, Operation & Coordination, Intervention & Follow-up and Recruit & Enrolment*. This RfP was largely disseminated on public websites (including IMI), specialised websites, as well as circulated by partners and donor on social media.

A webinar with further explanation of the project & RfP was held on 6 Jan 2021.

The Open call closed on 15 January 2021.

Figure 2. RfP as launched on the Trials@Home website



Step 1: RfP / Submission to Open call

First selection by pre-defined knock-out criteria
All submissions received, were checked for completeness and whether they met one or more of the pre-defined knock-out criteria. One (1) proposal was rejected for not meeting those pre-defined criteria.

Set-up & Design

- *Operational feasibility and site selection*

Submissions were rejected if:
1) Not able to demonstrate prior cases of at least two different clinical trials wherein Operational Feasibility and Site Selection systems were successful.
2) Not able to demonstrate prior cases of at least two different clinical trials wherein Operational Feasibility and Site Selection systems were successful and met GCP standards
3) Demonstration of above systems do not conform to reviewers' expectations.

- *IMP supply*

Submissions were rejected if:
1) Not able to demonstrate prior cases of at least two different clinical trials wherein IMP was purchased (from study drug assignment to drug destruction) and met EMA inspection standards.
2) Demonstration of IMP management systems do not conform to reviewers' expectations.

Recruitment & Enrolment

- *Peer-to-peer (Participant -to-Participant) Network*

Submissions were rejected if:
1) not GDPR compliant
2) does not allow for Member Password and Login Identity
3) does not provide membership eligibility check

- *Ability to integrate App Solutions to ensure (depending on drug used) / ability to integrate data from smart cap devices tracking drug intake*

Submissions were rejected if:
1) is not compatible for IMP used in PILOT

- *Calendar integration to Participant s calendars / email inbox*

Submissions were rejected if:
1) unable to integrate into iOS and Android and all current digital calendars
2) unable to run on all current mobile as well as stationery devices

- *Participant Recruitment Service Provider capable of both digital and non-digital Participant Recruitment specialized for diabetes/metabolic disorders*

Submissions were rejected if:
1) no previous experience/expertise in metabolic/diabetes (2 clinical trials)
2) unable to demonstrate experience in
    a) digital
    b) conventional recruitment (at least 2 trials in relevant TA)
3) unable to demonstrate experience/solutions for Behavioural Targeting/Retargeting, SEO, influencers.

Intervention & Follow-up

- *IMP Logistics*

Submissions were rejected if:

1) Not able to demonstrate prior cases of at least two different clinical trials wherein IMP was used (from study drug assignment to drug destruction) and met EMA inspection standards.
2) Demonstration of IMP management systems do not conform to reviewers' expectations.
3) Non-compliant with GDPR
4) Non-compliant with 21 CFR part 11

Data acquisition & Processing

- *Data Collection Middleware Technology*

Submissions were rejected if:

1) Data integration capabilities with Clinpal and other selected internal or external systems are missing (e.g. appropriate APIs)
2) Multiple data sources collection is not supported (monitoring devices, wearables, sensors and apps) Not compliant with Data Quality and Data Privacy regulations

- *Data Transformation and Standardisation*

Submissions were rejected if:

1) Data integration capabilities with Clinpal and other selected internal or external systems are missing (e.g. appropriate APIs)
2) Multiple data sources are not supported
3) Not compliant with Data Quality and Data Privacy regulations

- *Data Analysis*

Submissions were rejected if

1) Data integration capabilities with other internal or external systems are missing (e.g. appropriate APIs)
2) Analytics capabilities, streaming analytics (e.g. for devices), "Business" Intelligence and Reporting capabilities are not present
3) Not compliant with Data Quality and Data Privacy regulations

Operations & Coordination

- *Operational Analytics*

Submissions were rejected if:

1) Not able to demonstrate operational performance oversight dashboards functionality

- *Study Oversight*

Submissions were rejected if:

1) Not able to demonstrate operational performance oversight dashboards functionality

Participant Engagement

- *Participant / study data return*

Submissions were rejected if:

1) Not compatible with any/all mobile devices
2) Not compatible with any/all browsers (latest version + previous still-supported common versions)
3) Language limitations

- *Engagement consulting services*

Submissions were rejected if:
1) Inexperience in Diabetes TA

- *Social Media capabilities*

Submissions were rejected if:
1) Inexperience in Diabetes TA

- *Conversational Artificial Intelligence (Conversational AI)*

Submissions were rejected if:
1) Not compatible with any/all devices
2) Not compatible with any/all browsers (latest version + previous still-supported common versions)
3) Language limitations
4) Infant product

Results

In total n=30 technology/service providers initially responded to the RfP , with good coverage over all BBB's. Based on the number of submissions per activity and overlap of submissions over the technologies were distributed over n=10 Assessment Committee's. All committees consisted of specialists from the related BBB subteams, integration/architecture experts and representatives from our CRO: Julius Clinical. The composition of the assessment committees is listed in Appendix 2.

Figure 3. Overview of Assessment Committees, the included activities and RfP submission coverage. This overview includes the 7 additional submissions we received after the 1st assessment round, described later in this document.

Figure 3. Overview of Assessment Committees

Step 2: Quality assessment survey

Assessment of the received proposals
The selection of the technology package and associated technology/service partners was conducted according to the guiding principles of fairness, transparency and independency.

A custom-made digital self-assessment form (tailored set of quality criteria based on the specific building block / building block activity) was sent to the technology/service provider. This form contained questions addressing:

1) General information of the technology/service and the technology/service provider
2) Generic quality criteria
3) Quality criteria relevant to the specific technology/service, based on the relevant BBB and specific activities within that BBB.

The form was sent as an Excel sheet, with a provisional time-frame of 1 week to return. For each of the questions, the technology/service provider was requested to provide as much documentation/proof as possible to support their claim (e.g. certificates, SOPs, procedures). Returned surveys and documentation were stored in the related assessment committee folders on MyProjectPlaza.

Based on the self-assessment survey, one submission was rejected. The others proceeded to the next step

Step 3: Reviewing materials including proposal, quality survey and supplementary documents

The assessment committee received the self-assessment portfolio of each technology/service provider, which included the results of the self-assessment form and all related documentation. Each member of the assessment committee was asked to add their first observational notes in a committee PowerPoint template on MyProjectPlaza. Figure 4. Shows an example of how individual observations were collected into a single slide per technology/service provider:

Figure 4. Example showing how individual observations by committee members are collected

Company #019 – Key observations

	Generic	BBB-activity specific (Platform to host public TA information)	BBB-activity specific (Abillity to integrate app solutions)	BBB-activity specific (Patient Recruitment Service Provider)	Vendor-specific (incl. pricing)
TB Observations	Device agnostic, EU offices in UK, Italy, Germany, specialize in digital health and digital biomarkers, worked on COVID-19 studies, strong focus on their own data capture app, are approved as class 1 medical device, app enables remote monitoring and data capture, no P2P offerings, calendar integration only partly	Not fully clear, but seems like they don't offer anything in this area at all	Offer their own app and mention integration of a wide range (>200) of medical devices	Pre-screening and trial information is mentioned on one slide, but unclear what their actual offering is and whether it fits our needs, patient recruitment and outreach marked as "partly" in assessment form	Pricing includes Company #019 patient app, which will likely directly overlap with ClinPal Total costs £ xxx Per patient cost £ xxx Includes patient app, patient web portal and dashboard functionality
TB Questions	Proposal mentions e-Consent, ePRO, biometric capture, telemedicine visits and questionnaires modules, overlap with ClinPal unclear			See above	
Observation TK	Company #019 seems to focus more on Digital Health and Digital Biomarker Collection,eConsent, ePRO, Telehealth, focusing on pre-screener validation rather than digital recruitment activities (patient outreach, landing page, pre-screener not specificaly mentioned, only high level "can do")	Not shown in presi	Able to offer/integrate various apps/devices	focusing on pre-screener validation rather than digital recruitment activities (patient outreach, landing page, pre-screener not specificaly mentioned, only high level "can do")	
Observation 4	More patient engagement tools/capacities than recruitment activities				
Observation KL	Not really focussing on recruitment, capabilities unclear	Not covered	Own app, how does it fit	Not covered	Overlap with internal architect, not clear what they offer on top of it
Observation FIS	EU GDPR compliant. ISO 13485:2016 and ISO/IEC 27001 certified. Modular App. They seem to be capable to do some of the requirements, but they don't explain them	Not included in the slides	Modular App infraestructure anables to have different configurations tailored to the study. Integration to >200 devices	Mentioned but not well explained	

Step 4: 1st Assessment committee meeting + rating

Procedure + rating

For each assessment committee an online meeting was scheduled. In this meeting the members were informed about the process and ratings by the committee lead. First, for each of the submissions, the individual observations (collected in 1 slide) were discussed, and new observations added. This was followed by an individual rating of the following questions:

1. *What grade would you give to this solution with regards to meeting the [activity name 1] (quality, technical, functional) requirements?* 0-10 points
2. *What grade would you give to this solution with regards to meeting the [activity name 2] (quality, technical, functional) requirements?* 0-10 points

Etc.

And the following question:

3. *What is your general impression of them as a technology/service provider ?* (1-5 Net Promotor Score)

After all individual ratings are collected a median score was calculated and the committee asked to provide their top 3 (with 3, 2, 1 points respectively) solution for each activity and to provide argumentation. The three technology/service providers with the highest total scores (sum of scores of all committee members) will be selected for the pitch round.

Results
An example of the assessment per committee is listed below. As a result of the first rating, n=15 technologies were admitted to the next round, and 14 submissions were rejected.

Example - Committee 1. Set-up & Design

Submissions Overview

Overview submissions

		Operational feasibility & site selection	Study branding
Company 023	Solution #023		
Company 004	Solution #004.1 Solution #004.2 Solution #004.3		
Company 005	Solution #005		
Company 014	Solution #014		

Company 023 – Key observations

	Generic	BBB-activity specific (Operational feasibility & site selection)	Vendor-specific (incl. pricing)
VR(on-going)	Sounds a subscription-based cloud service only and info would be accessible by Sponsor to drive next steps. Unclear capabilities, strengths or successful cases .	No details provided on previous cases or sources of information (variety of information in the public domain?) Proposal does not detail: Investigational Site Master File system, rather qualification tr aining and tracking system, accessibility by clinical te ams, site initiation visit processes tracking etc.	Pricing not disclosed until CDA is completed
Observation 2			
Observation 3			

Company 023 – Rating

Note: Please start rating individually (filling in X's) and calculate mean and fill that in down here

	1	2	3	4	5	6	7	8	9	10
What grade would you give to this solution with regards to meeting the Operational feasibility & site selection (quality, technical, functional) requirements?		X (GF)								
						Remarks Too limited in scope compared to the more comprehensive proposals from other vendors				
What is your general impression of them as a vendor ?		X (GF)								

Company 004 – Key observations

	Generic	BBB-activity specific (Operational feasibility & site selection)	Vendor-specific (incl. pricing)
VR(on-going)	Mature vendor, huge database includes antidiabetes key players (e.g. Lilly), knowledgable sites on pLatform driven by experience with key sponsors may drive efficiencies	Provide the tool for site feasibility and site selection system, not the service	Additional capabilities : SIP Safety & SIP eISF included in the pricing
Observation 2			
Observation 3			
Observation 4			
Observation 5			
Observation 6			

Company 004 – Rating

Note: Please start rating individually (filling in X's) and calculate mean and fill that in down here

	1	2	3	4	5	6	7	8	9	10
What grade would you give to this solution with regards to meeting the Operational feasibility & site selection (quality, technical, functional) requirements?					X (GF)					
						**Remarks** Sufficiently comprehensive proposal				
What is your general impression of them as a vendor ?				X (GF)						

Company 005 – Key observations

	Generic	BBB-activity specific (Operational feasibility & site selection)	Vendor-specific (incl. pricing)
VR(on-going)	Digital and AI tool considering competitor landscape , historical and public data – digital healthcare system – for Study Planning and Recruitment	database of sites that have experience in conducting decentralized/remote support, not a tool for feasibility process neither a service	Not a service, except the country advisor network (additional cost)
Observation 2			
Observation 3			
Observation 4			
Observation 5			
Observation 6			

Company 005 – Rating

Note: Please start rating individually (filling in X's) and calculate mean and fill that in down here

	1	2	3	4	5	6	7	8	9	10
What grade would you give to this solution with regards to meeting the Operational feasibility & site selection (quality, technical, functional) requirements?					X(GF)					
						**Remarks** Very unique resourcing for conventional and remote site selection.				
What is your general impression of them as a vendor ?				X (GF)						

Company 014 – Key observations

	Generic	BBB-activity specific (Operational feasibility & site selection)	BBB-activity specific (Study Branding)	Vendor-specific (incl. pricing)
VR (on-going)	Predictive Analysis Tool and integated e-survey	Unclear the source of information to database and how to address investigational site selection (both arms). Very limited information on tool and e-survey functionalities. No details around: Investigational Site Master File system, rater qualification training and tracking system.		Wide range of services, but how much is just list of prior consutancy projects? Non-EU vendor Consulting-led approach with an ITS solutions and services
Observation 2				
Observation 3				

Company 014 – Rating

Note: Please start rating individually (filling in X's) and calculate mean and fill that in down here

	1	2	3	4	5	6	7	8	9	10
What grade would you give to this solution with regards to meeting the Operational feasibility & site selection (quality, technical, functional) requirements?									X (GF)	
What grade would you give to this solution with regards to meeting the Study Branding (quality, technical, functional) requirements?							X (GF)			
						**Remarks** Most comprehensive proposal				
What is your general impression of them as a vendor ?					X (GF)					

Example - Committee 1. Set-up & Design / Final rating

1. Setup & design

	1	2	3	4	5	Comments	Rank
Company 023						Solution is covering just a piece, not robust. Not meeting our requirements. Database only (unclear how it was build), but they do not provide the service.	4
Company 004						Comprehensive platform, they have a lot of capabilities that we need for covering the scope. Pricing okay. However not fully clear if they are also able to provide the service. Promising, but in general some doubts about expertise related to time challenges in T@H. We should also have a look at the testimonials.	3
Company 005						Comfortable with what they are capable of. True reach on site selection, good involvement of patients, user friendly. However: very generic text, would like to hear more and let them explain They are proposing the database, but not a tool for site feasibility process?	2
Company 014						Impressive, they check all the boxes. They flex to our needs. Investigator friendly. However some things are unclear: we like to hear more how they will do it.	1

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IM [2] Trials@Home grant n° 831458.

Step 5: Technology/service provider pitch and demo

Procedure

All remaining technology/service providers ranked in as top-3 within their activity were invited to give a pitch for assessment committee members and other Trials@home consortium members that were interested. The duration of this moderated session was tailored based on the number of activities covered by each technology/service provider, but usually took 1 hour, with 25 minutes of pitch and 30 minutes Q&A. All technology/service providers were instructed to provide a hands-on demo, to describe the integration process and to answer questions raised from during the 1st committee meeting. All pitch sessions were recorded.

Additional technology/service providers invited
After the 1st assessment round for specific activity gaps, five technology/service providers were pro-actively invited to submit a targeted proposal. To prevent too much delay in the process, these technology/service providers were offered a fast-track assessment process, which means that they:

1) Could submit their proposal and receive the self-assessment survey
2) No separate 1st assessment committee meeting
3) All technology/service providers were invited to provide a pitch/demo

From these five technology/service providers, three actually provided a pitch.

In addition, two technology/service providers handed in a late first submission. These two technology/service providers were included in a reserve pool and eventually they were not invited to pitch.

Results
All eighteen pitches were recorded; shared with the entire consortium and on MyProjectPlaza.

Step 6: The Independent Internal Expert Evaluation Panel (IIEEP, or 'Decision Committee')

Procedure
The evaluation of proposals was done by an independent internal expert evaluation panel, the **Decision Committee**, specifically installed for this purpose by the ExBo (with the agreement of the Partner Assembly), leading to recommendations for the final 'technology package' to be deployed in the pan-EU pilot.

Assessment process
Subject to further detailing as part of this task and the Technology assessment in WP2 TECH, the conditions and evaluation criteria included:
- Applicants – if selected - should be able to complete the necessary accession process in a timely manner;
- Applicants should have 'freedom to operate';
- Applicants should be eligible for participation in IMI2-JU projects;
- Applicants should adhere to the procedures and timelines set in the Open call;
- Proposals will be evaluated according to common evaluation criteria and procedures, developed by WP2 TECH (D2.2.) as published in the Open call.

Results:
Depending on the independent expert evaluation and selection, the outcome of the open call could be that (part of) the technology package will not require the accession of new partners (e.g. the technology can simply be purchased from an external technology/service provider or an existing consortium partner offers the technology).

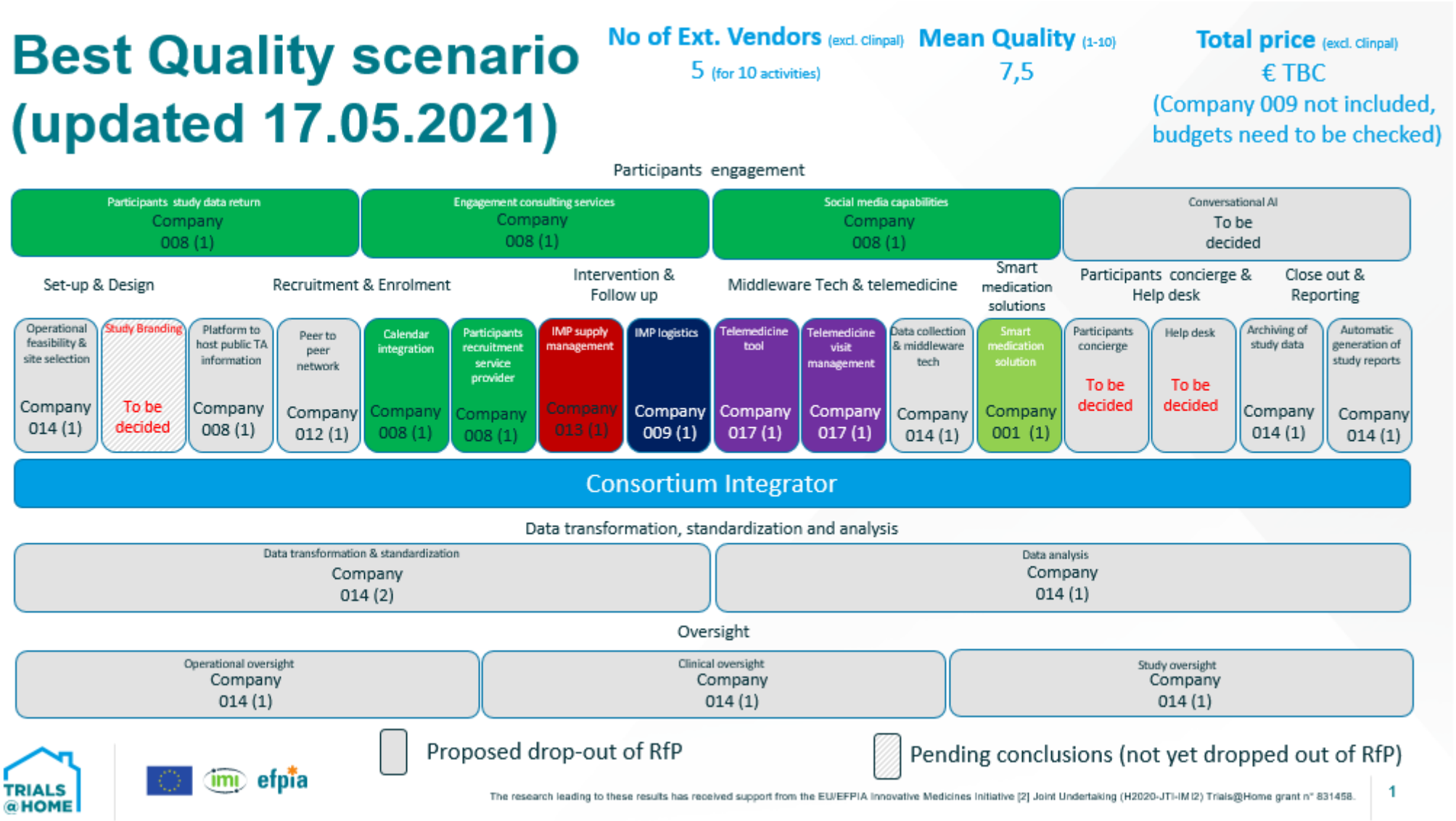
In case the 30% of the IMI-JU funding which is reserved to fulfil the tasks and expertise identified in the technology package, including tech and other innovative operational solutions, will not be utilised for this purpose in full, this reservation will be reallocated to other activities and partners in Trials@Home, following procedures as established in the Consortium Agreement

A preparatory session was held on March 26, 2021, to support the Decision Committee decision with additional insights about how companies were ultimately qualified (see step 1 to step 5 of the deliverable).

Following this meeting, the Decision Committee concluded, on 15 April 2021, to:
- run an additional benefit-risk assessment of the Telemedicine component to determine which of the two best qualified companies should be finally selected. The results of this assessment were submitted to a vote on 30 April 2021.
- agree to form an additional working group – composed of WP TECH, WP PILOT and WP PROMS members - to review whether some activities included in the RfP (labelled as "nice-to-have") could simply be purchase / delivered from an existing consortium partner and/or seem too immature to align with the pilot timelines, and thus should be excluded from the RfP. The recommendations from this working group were presented to the Decision Committee on 17 May 2021, and approved on 28 May 2021.

Conclusions

Figure 5. Example of likely final technological package with external technology/service providers



Appendix 1 - Trials@Home Request for Proposals full package

Trials@Home (EU/EFPIA Innovative Medicines Initiative – Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458) aims to reshape clinical trial design, conduct and operations, by developing and piloting standards, recommendations and tools for the definition and operationalisation of remote decentralised clinical trials (RDCTs) in Europe.

In a collaboration with 31 international partners, the EU/IMI project called Trials@Home will check the feasibility of fully remote decentralised Clinical Trials (RDCTs). For the execution of these RDCTs, technologies are needed. Some of them are already familiar and/or contracted by the project partners, but other RDCT technologies are not and need to be introduced in this project and pilot study. We are looking for these technologies, and that's why this Request for Proposals has been launched.

All the technologies are categorized in Basic Building Blocks (BBB) categories based on key functionalities within those building blocks, which are called activities. The scope of this RfP (also available here) contains the following BBB's / categories: Data Acquisition & Processing, Participant Engagement, Setup & Design, Closeout & Reporting, Operation & Coordination, Intervention & Follow-up and Recruit & Enroll. A description of these BBB's and required technologies can be found in the 'BBB profile' tabs below or can be downloaded at the bottom of this page.

- RCT - set-up & design
- RCT - recruitment & enrolment
- RCT - data acquisition & processing
- RCT - operations & coordination
- RCT - close-out & reporting
- RCT - Participant engagement
- RCT - intervention & follow-Up

Also we would like to receive a total price, that shows at least the following components:

- Give a clear definition of the scope and detailed assumptions
- Present an overview with costs per line item (no lump sum)
- Per task indicate the estimated hours and role per task (including hourly rates)
- If applicable, detailed information about license costs per month/year/user etc
- Transparency when you outsource parts to third parties
- Overview of other costs and pass though costs.
- You will be able to upload your proposal on the T@H website by clicking the 'Submit a proposal' button below.

After you have submitted a proposal for one or more of the requested technologies from the RfP , your proposal will be quickly checked on the knock-out criteria per relevant BBB. After a positive conclusion, you will receive a survey including instructions from Trials@Home. We kindly request you to fill in this survey, including remarks and documentation / proof to strengthen your answers, and return this form ultimately within 2 weeks.

Important Dates
Webinar with further explanation of the project & RfP : 6 Jan 2021, 3 PM CET
Deadline for submitting a proposal: 15 Jan 2021
Deadline for returning self-assessment form: 29 Jan 2021
Pitch + interviews: 16 Feb – 1 March 2021
Assessment process & criteria
After submitting a proposal and returning a completed survey, per BBB these documents per technology/service provider will be assessed. First a check will be done on the knock-out criteria that apply. Then, if passed, the formal assessment will start. Per BBB, an assessment committee is composed, that will score all proposals including a self-assement survey, based on pre-defined quality criteria and technology/service provider characteristics. You will find these quality criteria per BBB in the document 'Quality criteria per BBB'.

The self-assessment will result in a ranking per BBB. Numbers 1, 2 and 3 of this ranking per BBB will be invited for a pitch & interview. Their offer will be discussed, and the assessment team is allowed to adjust their scores per technology/service provider after this pitch and interview.

The technology/service provider that ranks number 1 after the pitch and interview, and is assessed as fit for purpose, will be nominated as candidate technology for the pan-European pilot study.

Please note that, due to different unforeseeable circumstances, T@H always has the possibility not to award a contract.

FYI, upon award of services, the attached contract template will be completed and executed. The standard terms and conditions are non-negotiable.

Questions
All interested technology/service providers may ask questions during this RfP . You can do so by sending your question per e-mail to: trialsathome@umcutrecht.nl.

Questions will be collected and answers will be – open to everybody – uploaded on the Trials@Home website.


2020-12-18 Quality Assessment Criteria.


2020-12-18 RfP document


BBB Profile - Closeout & Reporting


BBB Profile - Data Acquisition & Processing


BBB Profile - Intervention & Follo


BBB Profile - Operation& Coordination


BBB Profile - Participants Engagement


BBB Profile - Recruit & Enroll


BBB Profile - Setup&Design


JC - TECH Service Agreement template

Appendix 2 - Trials@Home Decision Committee members

	Role/expertise	
1	Project management academic	Annemarijn Douwes / Nathalie Vigot
2	PILOT industry lead	Megan Heath (& Linda Rutgrink)
3	PILOT academic lead + project lead	Mira Zuidgeest (& Arnela Suman)
4	TECH industry lead	Rebecca Jackson
5	TECH academic lead	Sten Hanke
6	Operational expert / CRO	Bas Nieuwenhuis
7	TECH platform	Karl Landert (& Bobby Davey)
8	GDPR/legal expert	Evert-Ben van Veen
9	Ethicist	Ghislaine van Thiel
10	Regulatory specialist	Tim de Smedt
11	Clinician/Investigator	Manuel Castro Cabezas
12	Trial budget specialist	Patrick Tierney
13	Project management industry	Philippe Bordes
14	BEST industry lead + project lead	Kim Hawkins
15	CODE industry lead	James Brook
16	Julius Clinical	Anton Bonefaas
17	Julius Clinical	Eric Houtman
18	Procurement specialist	Gerben Bekema
19	TECH RFP coordinator	Jaap Trappenburg
20	COVANCE	Joann Tundidor
22	Project PI	Rick Grobbee
21	Janssen	Rob Luscombe